

**MAY 17 2000**

K000121

Summary of Safety & Effectiveness  
IMMAGE® and Array® Systems Lipoprotein(a) Reagents and Calibrator

**1.0 Submitted By:**

Annette Hellie  
Staff Regulatory Specialist, Premarket Regulatory Affairs  
Beckman Coulter, Inc.  
200 S. Kraemer Blvd., W-104  
Brea, California 92822-8000  
Telephone: (714) 993-8767  
FAX: (714) 961-4123

**2.0 Date Submitted:**

17 Jan 2000

**3.0 Device Name(s):**

**3.1 Proprietary Names**

IMMAGE® Immunochemistry System Lipoprotein(a) (LPAX) Reagent  
Array® Systems Lipoprotein(a) (LPA) Reagent  
Lipoprotein(a) Calibrator

**3.2 Classification Name**

Lipoprotein immunological test system (21 CFR § 866.5600)  
Calibrator (21 CFR § 862.1150)

**4.0 Predicate Device(s):**

Candidate(s)	Predicate	Manufacturer	Docket Number
IMMAGE® and Array® Systems Lipoprotein(a) Reagents and calibrator	Apo-Tek Lp(a) <sup>TM</sup> ELISA Test Kit	Sigma Diagnostics	K970302

5.0 **Description:**

The IMAGE and Array System Lipoprotein(a) reagents, in conjunction with Lipoprotein(a) Calibrator, are intended for use in the quantitative determination of human lipoprotein(a) concentrations in human serum and plasma samples by rate nephelometry.

6.0 **Intended Use:**

Lipoprotein(a) (LPAX) Reagent, when used in conjunction with IMAGE® Immunochemistry Systems and Lipoprotein(a) Calibrator, is intended for the quantitative determination of human lipoprotein(a) in serum or plasma by rate nephelometry.

Lipoprotein(a) (LPA) Reagent, when used in conjunction with Array® Systems and Lipoprotein(a) Calibrator, is intended for the quantitative determination of human lipoprotein(a) in serum or plasma by rate nephelometry.

Lipoprotein(a) Calibrator (LPA CAL), when used in conjunction with Lipoprotein(a) reagents, is intended for use on Array®, Array® 360, and IMAGE® Immunochemistry Systems for the calibration of these reagents.

**Clinical Significance:**

Measurement of lipoprotein(a) in conjunction with other lipoprotein tests, is of diagnostic significance when assessing atherosclerotic cardiovascular disease in specific populations.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

	SIMILARITIES	
IMAGE and Array System LPA Reagents	Intended use	Same as Apo-Tek Lp(a) Reagent
	Sample type (serum & plasma)	
	Sample storage	

DIFFERENCES		
IMMAGE and Array System Lipoprotein(a) Reagents	Methodology	The Apo-Tek Lp(a) uses ELISA while the Beckman Coulter systems use nephelometry.
	Analytical Range	The Beckman Coulter method range is 2 - 128 mg/dL while the Apo-Tek range is 0.3 - 100 mg/dL.
	Calibration	The Beckman Coulter methods use a single point calibration while the Apo-Tek requires 6 levels.
	Antibody source	The Beckman Coulter antibody is rabbit while the Apo-Tek uses an anti-apo(a) murine capture antibody and a labeled polyclonal anti-apo(b) sheep antibody.

#### 8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, linearity, and imprecision experiments.

#### Method Comparison Study Results

Analyte	Slope	Intercept	r	n	Predicate Method
IMMAGE LPAX Reagent	0.810	0.866	0.940	400	APO-Tek Lp(a)
Array LPA Reagent	0.855	-0.084	0.956	416	APO-Tek Lp(a)

**IMMAGE System LPAX Estimated Imprecision**

<b>Sample</b>	<b>Mean (mg/dL)</b>	<b>S.D. (mg/dL)</b>	<b>%C.V.</b>	<b>N</b>
<b>Within-Run Imprecision</b>				
Level 1	6.57	0.207	3.2	80
Level 2	40.0	1.10	2.7	80
Level 3	88.8	2.67	3.0	80
<b>Total Imprecision</b>				
Level 1	6.57	0.232	3.5	80
Level 2	40.0	1.24	3.1	80
Level 3	88.8	3.19	3.6	80

**Array System LPA Estimated Imprecision**

<b>Sample</b>	<b>Mean (mg/dL)</b>	<b>S.D. (mg/dL)</b>	<b>%C.V.</b>	<b>N</b>
<b>Within-Run Imprecision</b>				
Level 1	6.07	0.216	3.6	80
Level 2	47.5	1.01	2.1	80
Level 3	89.8	1.53	1.7	80
<b>Total Imprecision</b>				
Level 1	6.07	0.542	8.9	80
Level 2	47.5	1.52	3.2	80
Level 3	89.8	2.16	2.4	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 17 2000

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Annette Hellie  
Staff Regulatory Specialist  
Beckman Coulter, Inc.  
200 S. Kraemer Boulevard, W-104  
P.O. Box 8000  
Brea, California 92822-8000

Re: K000121  
Trade Name: IMAGE® Immunochemistry System  
Lipoprotein(a) (LPAX) Reagent  
Array® Immunochemistry System  
Lipoprotein(a) (LPA) Reagent  
Lipoprotein(a) Calibrator  
Regulatory Class: II  
Product Code: DFC, JIS  
Dated: April 4, 2000  
Received: April 5, 2000

Dear Ms. Hellie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

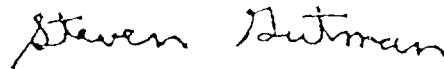
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized "S" and "G".

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000121

Device Name: **IMMAGE® Immunochemistry System  
Lipoprotein(a) (LPAX) Reagent**

Indications for Use:

**Lipoprotein(a) (LPAX) Reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and Lipoprotein(a) Calibrator, is intended for the quantitative determination of human lipoprotein(a) in serum or plasma by rate nephelometry.**

**Clinical Significance:**

**Measurement of lipoprotein(a) in conjunction with other lipoprotein tests, is of diagnostic significance when assessing atherosclerotic cardiovascular disease in specific populations.**

*Jean Cohen*  
(Division Chief)  
Division of Clinical Laboratory Devices  
510(k) Number K000121

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—  
*Concurrence of CDRH, Office of Device Evaluation (ODE)*

Prescription Use ✓  
(per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_  
Optional Format 1-2-96

510(k) Number (if known): K000121

Device Name: **Array® Immunochemistry System  
Lipoprotein(a) (LPA) Reagent**

Indications for Use:

**Lipoprotein(a) (LPA) Reagent, when used in conjunction with Array® Systems and Lipoprotein(a) Calibrator, is intended for the quantitative determination of human lipoprotein(a) in serum or plasma by rate nephelometry.**

**Clinical Significance:**

**Measurement of lipoprotein(a) in conjunction with other lipoprotein tests, is of diagnostic significance when assessing atherosclerotic cardiovascular disease in specific populations.**

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— *Concurrence of CDRH, Office of Device Evaluation (ODE)*

Prescription Use ✓  
(per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_  
Optional Format 1-2-96

510(k) Number (if known): K000121

Device Name: **Lipoprotein(a) Calibrator**

Indications for Use:

**Lipoprotein(a) Calibrator (LPA CAL), when used in conjunction with Lipoprotein(a) reagents, is intended for use on Array®, Array® 360, and IMAGE® Immunochemistry Systems for the calibration of these reagents.**

**21 CFR 862.1150 Calibrator**

**(a) Identification. A calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.**

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— *Concurrence of CDRH, Office of Device Evaluation (ODE)*

Prescription Use ✓  
(per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_  
Optional Format 1-2-96